IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO WAVE 4 CASES ON EXHIBIT A TO PLAINTIFFS' MOTION	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' REPLY IN FURTHER SUPPORT OF PLAINTIFFS'MOTION TO EXCLUDE OR OTHERWISE LIMIT THE OPINIONS AND TESTIMONY OF DEFENSE EXPERT BRIAN PARKER, M.D.

In further support of their Motion to exclude or otherwise limit the opinions and testimony Defendants' expert, Dr. Brian Parker, M.D., Plaintiffs state as follows:

ARGUMENT

I. Dr. Parker's General Opinions About Risks That Are Within the Common Knowledge of Physicians Should Be Precluded or Limited.

Dr. Parker intends to offer testimony regarding the potential risks of the TVT-O and TVT-S devices that "attend any pelvic reconstruction—and that are common knowledge among surgeons performing the procedures at issue here." *See* Defs.' Opp. At 2. Dr. Parker has no reliable basis upon which to offer these opinions. *See Trevino v. Boston Scientific Corp*., No. 2:13-cv-01617, 2016 WL 2939521, at *39, (S.D. W. Va. May 19, 2016) (excluding opinion that "surgeons are well aware of clinical implications of complications" when expert has not established opinions are the result of a reliable methodology). In support of their arguments, Defendants suggest that Dr. Parker relied not only on his extensive clinical experience "but also a thorough review of the medical literature." Defs.' Opp. At 1. However, Dr. Parker admits that

there were a lot of materials provided to him by Ethicon and he "may not have seen every little bit of everything." Parker 3/14/17 Dep. Tr. at Parker 3/14/17 Dep. Tr. at 12:16-13:4.

Dr. Parker has made statements during his deposition testimony regarding complications and side effects he considered "well-known" in the medical community. (*See* Parker 3/14/17 Dep. Tr. at 143:8-158:3.) However, Dr. Parker has not demonstrated that he followed a reliable methodology to reach these sweeping conclusions. Instead, Dr. Parker so much as admitted that most doctors do not have his same level of knowledge regarding these products and procedures – which means his personal knowledge of the complications is not necessarily shared by all surgeons. *See* Parker 3/14/17 Dep. Tr. at 21:4-20 and 96:21-98:11; also *see Id*. at 25:14-27:11 (even though he admits that he hasn't really treated many complications, has never been involved with any studies or registries regarding slings); *Id*. at 58:16-59:4 (In his hands and in the studies he's seen, adverse events are low); *Id*. at 146:10-147:1 (admits he has no way of knowing if the physicians he trained from ever looked at the IFU). Dr. Parker cannot reliably testify, simply based on personal knowledge, as to the "common knowledge of all doctors" – especially if he is differently positioned based on his experience and expertise. *See Trevino,* 2016 WL 2939521, at *9 (explaining that an expert "may not solely rely on his personal observations when he seeks to provide broad opinions.") Dr. Parker fails to reference or utilize any standards that can be objectively applied by others to test his opinions, which are nothing more than net opinions. Therefore, Dr. Parker's opinions concerning risks within the common knowledge of physicians are unreliable and should be excluded.

II. Dr. Parker's General Opinions on the Design and Scientific Properties of the TVT-O and TVT-S Devices Should Be Precluded or Limited.

Dr. Parker does not have any specialized education or training or applicable relevant experience specifically related to the design of polypropylene mesh devices and biomaterials

issues, including degradation, contraction, shrinkage, porosity and adequate weight of mesh materials. First, Dr. Parker lacks basic, first-hand knowledge of these topics. Second, Dr. Parker no longer implants the TVT-O, TVT-S or any other Ethicon manufactured pelvic mesh devices. *See* Parker 3/14/17 Dep. Tr. at 18:12-21. Moreover, Dr. Parker acknowledged, at his deposition, that he had very limited experience in removal of polypropylene mesh. *See* Parker 3/14/17 Dep. Tr. at 21:4-22:2; 23:3-25:3; and 25:14-27:11. Unlike other experts in his field, Dr. Parker has had very little opportunity to form an opinion based on clinical experience because he has so infrequently been involved in the removal of mesh.

Further, Dr. Parker is not qualified to opine on degradation because he admittedly assumes that polypropylene does not degrade and that he only first became aware of the potential for mesh to degrade after being hired by Ethicon to write his report on this matter:

> Q. When you were being trained on devices manufactured by Ethicon, you understood that those devices all contained the same type of polypropylene; the TVT, the TVT obturator and TVT-S devices all contained the same type of mesh, which was the prolene mesh, correct?
> A. Yes.
> Q. And you knew that those were made from the same material that the sutures were made from. Is that accurate?
> A. Yes.
> Q. And were you aware back at that time of the potential for the sutures to become degraded?
> A. I disagree with that. I would have to think that something that would be used as a suture for vessels would have to be proven to be non-degradable. And so based on that and the fact that I've seen the mesh after it's been removed and there's no visible change in the mesh, I really can't agree with the initial premise of your question.
> Q. I think my question was just simply did you know that the polypropylene had a tendency to degrade after implantation back when you were being trained on the devices.
> A. Well, are you basing it on that one

> article?
> Q. Well, I'm just asking --
> A. Because from a clinical standpoint, we would assume all surgeons are trained to look at prolene suture as a non-degradable suture. So that is the premise that I came into this with and continue to use, not that -- well, I'll just stop with that.
> Q. When was the first time you had heard of the potential of degradation with regard to polypropylene?
> A. Not until late last year.
> Q. When you began preparing for your report?
> A. Yes, ma'am.

Parker 3/14/17 Dep. Tr. at 33:20-35:7.

Dr. Parker's opinions regarding mesh design, including the potential for mesh contraction, shrinkage, as well as porosity and the appropriate weight of mesh remain unreliable and unhelpful to the jury. Dr. Parker bases the majority of his opinions on what he has or has not observed in his practice and what he learned through society guidelines. Parker 3/14/17 Dep. Tr. at 28:19-31:17; 38:8-39:16; 109:8-113:9; 113:10-115:3; 115:9-119:16; 138:1-140:19; 140:20-143:7. Dr. Parker's clinical observations related to biomaterials issues are based on the kind of unscientific examination that have routinely been excluded by this Court. *See e.g., Tyree v. Boston Sci. Corp*., 54 F. Supp. 3d 501, 554 (S.D. W. Va. 2014) (excluding opinions regarding explanted mesh when opinions not derived using "scientific methods"). Dr. Parker's complete lack of experience relating to the design of the TVT, TVT-O and TVT-S—or any mesh device—renders his opinions on design inadmissible. *See Tyree*, 54 F. Supp. 3d at 581 (excluding expert's opinion on design of Obtryx after expert admitted he lacked experience with sling design); *see also Robbins v. Boston Sci. Corp*. No. 2:12-cv-01413, 2016 WL 3189248, at *22 (S.D. W. Va. June 7, 2016) (excluding expert's opinion regarding mesh design where expert testified he had not designed any POP products and rejecting argument that expert had sufficient

experience with pelvic floor kits to opine as to device design). Therefore, his opinions on the design and scientific properties of mesh devices should be excluded.

For the reasons stated in Plaintiffs' original Motion to exclude or otherwise limit the opinions and testimony of Defendants' expert, Dr. Brian Parker, M.D., Dr. Parker's opinions regarding the design, material properties of polypropylene mesh including degradation, cytotoxicity, contraction of mesh, adequacy of pore size and weight of the mesh, as well as a lack of clinical difference between laser and mechanically cut mesh, should be excluded.

CONCLUSION

For these reasons, Plaintiffs ask that this Court grant their motion and exclude or otherwise limit the opinions and testimony of Dr. Parker. Plaintiffs further request all other relief to which they are entitled.

Respectfully submitted,

/s/ Bryan F. Aylstock
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
baylstock@awkolaw.com
rbaggett@awkolaw.com
Attorneys for Plaintiffs

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CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on May 4, 2017, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/ Bryan F. Aylstock
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com